

# Notice of Allowability

Application No.

09/727,461

Examiner

Dave T. Nguyen

Applicant(s)

HENDRIKS, MARC

Art Unit

1632

## -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to March 15, 2004.
2. ☒ The allowed claim(s) is/are 1,2,4-6,8,9,11-14,25,26,28-30,32,33,35-38 and 49.
3. ☒ The drawings filed on \_\_\_\_\_ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
  1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

### Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date \_\_\_\_\_
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

Claims 7, 15-24, 31, 39-48, 53, and 54 have been canceled; Claims 1, 25, and 49 have been amended by the amendment filed March 15, 2004.

Claims 1, 2, 4-6, 8-14, 25-26, 28-30, 32-39, 49 and 50 are pending.

To the extent that Applicant's response is applicable to the currently amended base claims, the response, particularly pages 13-16, together with the totality of the prior art of record has been considered fully by the examiner, and is found persuasive for the withdrawal of the outstanding prior art rejections. The examiner further acknowledges that while it is well-recognized in the prior art that a polymer coated medical device has been employed as a delivery device for a local delivery of a biologically active agent such as a nucleic acid sequence, see Goldstein, US 6,143,037, the prior art of record neither teaches nor suggests a person of ordinary skill in the art to employ a medical device comprising a DNA encoding an antimicrobial peptide for implantation so as to treat a microbial infection in a subject, let alone a teaching of a medical device coated with a polymer film, wherein a portion of which polymer is associated with a DNA encoding an antimicrobial peptide. The totality of the prior art, as exemplified in Chudzik (US 20030031780 A1) and Siman, does teach and recognize a need to employ a more biocompatible implantable device so as to reduce a microbial infection. However, the teaching is not the same as the subject matter being sought in the presently pending claims. In fact, a DNA encoding an antimicrobial peptide does not itself exhibit an antimicrobial activity but rather is a vehicle used to subsequently express an antimicrobial peptide, which by itself exhibits an antimicrobial activity. Another closest prior art, Gunzburg, WO 96/28563, is primarily focused on a

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pharmaceutical composition comprising a pharmaceutically acceptable buffer and a retroviral vector expressing an antimicrobial peptide for treatment of a microbial infection. However, neither Gunzburg nor any prior art of record teaches, suggests, or provides a motivation to employ an antimicrobial peptide expressing retroviral vector on a medical device, let alone a teaching or suggestion of an administration of medical device comprising on its exterior surface polymeric film/retroviral vector complexes. Thus, the species restriction has been withdrawn by the examiner, and the presently pending claims are free of the prior art of record.

### **Examiner' s Amendment**

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Attorney Paul H. McDowall on April 8, 2004.

The examiner's amendment is to mainly correct the duplication of claims and typographical errors.

#### **In the claims:**

Claims 10, 34, and 50 have been canceled.

In claim 49, line 6, delete the second comma “,”.

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As the result of the examiner's amendment, claims 1,2,4-6,8,9,11-14,25,26,28-30,32,33,35-38 and 49 are allowable.

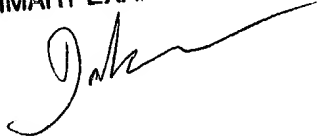
Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Dave Nguyen* whose telephone number is **571-272-0731**.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *Amy Nelson*, may be reached at **571-272-0184**.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center number, which is **703-872-9306**.

Any inquiry of a general nature or relating to the status of this application should be directed to the *Group receptionist* whose telephone number is **(703) 308-0196**.

DAVE T. NGUYEN  
PRIMARY EXAMINER



Dave Nguyen  
Primary Examiner  
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